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WHOLE BLOOD ANALYSIS OF PROSTATE SPECIFIC ANTIGEN SPOTTED ON A SOLID SUPPORT

Abstract:

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BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to screening or testing for prostate specific antigen (PSA). More specifically, the present invention relates to a method for screening for PSA from whole blood spotted on a solid support. Additionally, the present invention relates to a test kit for screening or testing for PSA using the solid support.

2. Description of the Prior Art

Prostate adenocarcinoma accounts for the majority of malignancies in males over the age of 65. Yearly screening for prostate cancer is recommended after the age of 45. There has been considerable effort toward identifying suitable prostate cancer markers to assist in screening and diagnosing this disease.

PSA is recognized as the most sensitive marker of prostatic adenocarcinoma (Brawer MK. Cancer 1993; 71 (suppl):899-905; Oesterling JE. J Urol 1991; 145:907-23). PSA is also recognized as a proven screening vehicle (Gann PH, *et al.* J Amer Med Assoc 1995; 273:289-94.; Catalona WJ, *et al.* J Urol 1994; 151:1283-90). It is the most sensitive front line test for identifying prostate gland-contained, and hence presumably curable, cancer. PSA is also useful in detecting clinically significant cancers as opposed to latent, indolent microcarcinomas often found on autopsy. PSA is also superior to the common office practice of digital rectal examination (DRE). For example, Labrie *et al.* (Clin Invest Med 1993; 16: 425-39) showed that 97% of cancers detected at annual follow-up by DRE plus PSA testing were PSA-positive. Thus, only a minimal benefit accrues from including DRE in the medical evaluation.

Prostate specific antigen has also been used to detect the onset of puberty in children between ages 8 and 25 years (*Vieira J.G.H.*, et al. J Clin Endocrinol Metab 1994;78:1185-1187). Since PSA is an androgen-dependent protein and its expression is up-regulated by androgenic steroid hormones, women with hyperandrogenic syndromes may also have elevated PSA in their serum. Additionally, PSA has now been found in the serum and extracts from breast tumors (*Diamandis E.P., Yu H.* J Clin Endocrinol Metab 1995;80:1515-1517), indicating that it has utility in breast cancer screening and monitoring.

Currently, PSA is tested by first collecting a blood specimen via venipuncture phlebotomy. This usually necessitates that the individual to be tested make a physician office or hospital visit. The blood so collected is usually processed for shipment to a suitable clinical